REMARKS

This preliminary amendment accompanies a Request for Continued Examination (RCE) and is responsive to the final Office action mailed February 2, 2010. A Notice of Appeal was filed on July 30, 2010.

Claims 1-16 and 18-26 are pending. Claims 4-11 previously were withdrawn from consideration in response to a restriction requirement. Claim 17 has been canceled. Claims 1, 20 and 24 have been amended. Claim 25 is new. Support for the new and amended claims can be found, for example, in FIG. 1, corresponding portions of the detailed description and in the last paragraph on page 4. No new subject matter has been added.

Applicant asks that all claims be examined in view of the amendment to the claims.

As an initial matter, the undersigned attorney thanks the Examiner for his cooperation during a telephone interview conducted on September 16, 2010. Participants in the telephone interview included the undersigned attorney, Dr. Sybil Lombillo, Esq. and Dr. Brian P. Jacob, the inventor in the present application.

During the interview, the Examiner agreed that if the claim were amended as presented herein then the application would be in condition for allowance for at least the reasons discussed below.

During the interview, the Examiner expressed concern about whether the specification contains adequate support for the subject matter of dependent claim 17. Applicant does not concede that the specification does not include adequate support for dependent claim 17. Nevertheless, in order to advance prosecution toward an allowance, Applicant has canceled claim 17.

In the Office action, claims 1, 2 and 12-18 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,071,408 (Ahmed) in view of U.S. Patent No. 5,380,290

(Makower). As discussed below, claim 1, as amended, should be allowable over the cited references.

First, claim 1, as amended, recites an endoluminal protection and access device for positioning within a lumen of a gastrointestinal tract. The device has an access member with an outer wall defining an internal lumen. The access member is sufficiently flexible to permit navigation through a tortuous path.

An example of the claimed subject matter is shown in FIG. 1, which shows an access device 10 that has an access member 12 with an outer wall 14 defining an internal lumen 16. The access member is sufficiently flexible to permit navigation through a tortuous path (*e.g.*, a tortuous portion of a gastrointestinal tract). In a typical implementation, this flexibility advantageously helps make the access member suitable for accessing various operative sites in the often tortuous gastrointestinal tract.

As discussed below, neither the Ahmed patent nor the Makower patent, alone or in combination, disclose or render obvious the claimed subject matter.

The Ahmed patent discloses a surgical instrument 80 that can be used to insert a portion of a medical valve into a patient's eye. (2:3-5; and FIG. 11) The instrument 80 has a handle 82 and a needle-like body member 84 with an elongated slot 86 in a side wall 84a thereof. (7:3-23)

It is clear that the needle-like body member 84 in Ahmed's surgical instrument 80 is not flexible to permit navigation through a tortuous path, as now recited in claim 1. Nor would a person of ordinary skill have had any reason to modify Ahmed's surgical instrument to include the claimed subject matter. As mentioned above, Ahmed's surgical instrument 80 is used to insert a portion of a medical valve into a patient's eye. The surgical instrument 80 does not encounter a tortuous paths in the patient's eye and, therefore, would not realize the same benefit from being flexible as the claimed access device (for positioning within a lumen of a gastrointestinal tract) realizes.

Moreover, somehow making Ahmed's needle-like body flexible likely would have compromised its ability to perform its intended function and made it more dangerous, particularly for use in a patient's eye.

In view of the foregoing, Applicant submits that a person of ordinary skill would have had no reason to modified the surgical instrument 80 disclosed in the Ahmed patent in a manner that would have led to the claimed subject matter.

The Makower patent discloses a body access device 10 that has a syringe 12 coupled to a needle 14 with a slot 26 that has an enlarged opening 36 at one end to accommodate a guidewire 24 or the like.

It is clear that the needle 14 in Makeower's body access device 10 is not flexible to permit navigation through a tortuous path, as now recited in claim 1. Nor would a person of ordinary skill have had any reason to modify Makeower's body access device 10 to include the claimed subject matter. Makeower does not disclose or suggest that the body access device 10 might be used in applications where it would encounter a tortuous paths. A person of ordinary skill, therefore, would have had no reason to modify Makeower's body access device in a manner that would have led to the claimed subject matter.

Accordingly, the same subject matter is missing from Ahmed's surgical instrument as is missing from Makeower's body access device. Moreover, a person of ordinary skill would have had no reason to modify either device to obtain the claimed subject matter.

Claim 1 should be allowable for at least the foregoing reasons.

Claim 1 should be allowable for the following additional reasons as well.

Claim 1 recites an endoluminal protection and access device that includes an access member with an outer wall that defines an internal lumen and a window adjacent a distal end of the access member. The window is in communication with the internal lumen. An example of the claimed subject matter is shown in FIG. 1, which shows an endoluminal protection and access device that includes an access member 12 with an outer wall 14 that defines an internal lumen and a window 24 in communication with the internal lumen and adjacent a distal end 20 of the access member.

In a typical implementation, the claimed subject matter provides mucosal protection and lumen stabilization for an anastomosis site. Moreover, typical implementations generally can

increase the precision with which a zone of safety for performing certain ostomy-related surgical techniques is located and visualized. Implementations of the claimed subject also can be used to stabilize a future anastomosis site, permit precise needle puncturing in a colostomy reversal procedure, and protect a luminal wall of a patient's colon opposite the needle puncture from inadvertent injury during the colostomy reversal procedure. *Id.*

The Ahmed patent and the Makower patent, alone or in combination, do not disclose or render obvious the claimed subject matter.

The Ahmed patent discloses a surgical instrument 80 that can be used to insert a medical valve, for example, into a patient's eye to treat glaucoma. (2:3-5; and FIG. 11) The instrument 80 has a handle 82 and a needle-like body member 84 with an elongated slot 86 in a side wall 84a thereof. (7:3-23) The slot 86 allows an inlet tube 18 (of the valve) to be placed within the needle-like body member 84 along a U-shaped channel 88 in the needle-like body member 84. The slot 86 and channel 88 each have a width that is essentially equal to the diameter of the inlet tube 18 so that, with the inlet tube lying in the channel, there is a snug, friction fit. Thus, when the instrument 80 is inserted into the patient's eye, fluid will enter the open end of the inlet tube 18 and flows through the inlet tube 18 rather than between the wall of the channel 88 and the wall of the tube.

The outer wall of Ahmed's surgical instrument 80 does not define a window in communication with its internal lumen adjacent a distal end thereof, as recited in claim 1 of the present application. The Office action itself appears to concede this point.[1] The Office action alleges, however, that it would have been obvious to modify Ahmed's surgical instrument 80 to include add a window at a proximal end of the slot 86 in Ahmed's surgical instrument 80 in view of what is disclosed in Makower. Applicant respectfully disagrees.

The Makower patent discloses a body access device 10 that includes a syringe 12 coupled to a needle 14 with a slot 26 that has an enlarged opening 36 at one end to accommodate a guidewire 24 or the like.

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[1] The Office action states, "Ahmed fails to disclose a window at the proximal end of the slot."

A person of ordinary skill would have had no reason to modify Ahmed's surgical instrument 80 to include an enlarged opening (such as the enlarged opening 36 in Makower's device) because doing so would have been in direct contradiction to the Ahmed's teachings and may have compromised the instrument's effectiveness in performing its intended functions.

As mentioned above, the Ahmed patent emphasizes that the slot 86 (and the U-shaped channel 88) has a width that is essentially equal to the diameter of an inlet tube 18 that gets inserted into the channel 88 during use. *See* FIGS. 11 and 12. Since the inlet tube 18 clearly has a continuous diameter along its entire length, the slot 86 also has a continuous diameter along its length. The Ahmed patent explains that this arrangement enables the inlet tube 18 to be inserted in the channel and secured with a snug, friction fit. Accordingly, when the instrument 80 is inserted into the patient's eye, fluid will enter the open end of the inlet tube 18 and flow through the inlet tube 18 rather than between the wall of the channel 88 and the wall of the inlet tube 18.

In view of the foregoing disclosure, a person of ordinary skill would not have modified the slot 86 in Ahmed's instrument 80 to add an enlarged opening (such as the enlarged opening 36 in Makower's device) because doing so would have been in direct contradiction to Ahmed's emphasis on the width of the slot 86 being essentially equal to the diameter of the inlet tube.

Moreover, a person of ordinary skill would have recognized that adding an enlarged opening (such as the enlarged opening 36 in Makower's device) to a proximal end of the slot 86 in Ahmed's instrument 80, as the Office action alleges would have been obvious, actually would have been undesirable. As mentioned above, Ahmed's instrument 80 is used to insert an inlet tube 18 of a valve into a patient's eye:

> To use the instrument . . ., with the tube 18 in the channel 88, the surgeon simply inserts the shape tip 85 of the instrument 80 into the eyeball to bring the inlet tube 18 into the intraoccular chamber 20 of the eye. The surgeon then simply withdraws the instrument. As he does this, the inlet tube 18 remains in the eye, with the surrounding tissue grasping the inlet tube as the instrument 80 is withdrawn. The valve body 11 is then placed beneath a sclara flap 90 (FIGS. 13 and 14) which is cut from the exterior of the eye ball.

(7:24-33) Adding an enlarged opening (such as the enlarged opening 36 in Makower's device) to a proximal end of the slot 86 in Ahmed's instrument 80 could cause a variety of

undesirable complications in this procedure. For example, the slot 86 would have additional contours that could grab the inlet tube 18 as the instrument is being withdrawn. This could cause the inlet tube 18, which is supposed to remain in the eye, to be pulled out when the instrument is pulled out. This would be inconvenient for the surgeon and potentially very dangerous to the patient.

For these reasons, a person of ordinary skill would not only consider the suggested modifications to be non-obvious, they would consider such modifications to be undesirable.

Claim 1 should be allowable for at least the foregoing reasons.

Additionally, the device of claim 1 includes structural features that render it suitable for gastrointestinal applications. In this regard, claim 1 recites an access member with a distal end that is "sufficiently blunt to prevent perforation of the gastrointestinal lumen during positioning of the device," and "a cross-sectional dimension transverse to the longitudinal axis and a rigidity and a size of the cross-sectional dimension sufficient to stabilize the gastrointestinal lumen upon positioning therein to maintain patency of the gastrointestinal lumen." (emphasis added)

Neither Ahmed nor Makower mentions gastrointestinal applications, such as the endoluminal colostomy reversal procedure disclosed at pages 8-10 of the present application.

As discussed above, the Ahmed reference discloses to a surgical instrument 80 used to treat a patient's eyes (not his or her patient's gastrointestinal system). The Makower patent discloses a vascular access device 10, which is "used to obtain percutaneous canalization of blood vessels to facilitate the passage of catheters through tissue and vascular walls while eliminating the need to thread multiple components over a guidewire." (1:5-12) Neither Ahmed nor Makower, therefore, discloses a surgical instrument or device with a distal end that is "sufficiently blunt to prevent perforation of the gastrointestinal lumen during positioning of the device," as recited in claim 1. Indeed, the distal end of Ahmed's surgical instrument and the distal end of Makower's device are specifically designed for piercing. *See, e.g.*, Ahmed's FIG. 12 and Makower's FIG. 1.

Moreover, since neither Ahmed's surgical instrument 80 nor Makower's device are used in gastrointestinal applications, neither Ahmed nor Makower discloses a device with "a cross-sectional dimension transverse to the longitudinal axis and a rigidity and a size of the cross-sectional dimension sufficient to stabilize the gastrointestinal lumen upon positioning therein to maintain patency of the gastrointestinal lumen," as recited in claim 1.

Nor would these features have been obvious in view of Ahmed or Makower, because of the very different considerations in gastrointestinal procedures (such as the endoluminal colostomy reversal procedure disclosed in the present application) than in eye procedures (such as disclosed in Ahmed) or vascular access procedures (such as disclosed in Makower).

Claim 1 should be allowable for at least the foregoing reasons as well.

Claim 2 and 12-18 depend from claim 1 and, therefore should be allowable for at least the same reasons as claim 1.

Claim 20, 21 and 23 also were under 35 U.S.C. §103(a) as unpatentable over Ahmed in view of Makower. As discussed below, Applicant respectfully disagrees with these rejections.

Claim 20 recites a device with an elongated access member having a distal end formed so as to minimize perforation of a body lumen (i.e., a lumen in the patient's body).

Neither the Ahmed patent, nor the Makower patent, alone or in combination, disclose or render obvious the claimed subject matter.

Ahmed discloses to a surgical instrument 80 that is specifically designed for piercing a patient's eyes. *See* Ahmed, FIG. 12. Similarly, Makower discloses a vascular access device 10 specifically designed for piercing a patient's skin 20 and blood vessels 22. *See* Makower, FIG. 1. Neither Ahmed's surgical instrument 80, nor Makower's vascular access device 10, therefore, has a distal end formed so as to minimize perforation of a body lumen.

Nor would a person of ordinary skill have considered it obvious to modify either Ahmed's surgical instrument 80 or Makower's vascular access device 10 to include a distal end formed so as to minimize perforation of a body lumen, as recited in claim 1, because doing so

would have frustrated their ability to perform the very function they are intended to perform (*i.e.*, piercing).

Claim 20 should be allowable for at least the foregoing reasons.

Additionally, claim 20 recites an elongated access member having an outer wall that defines a longitudinal bore. The outer wall has a window communicating with the longitudinal bore and a slot communicating with the longitudinal bore and extending from the window to the distal end. The window defines a radial arc in the range of about 90 degrees to about 180 degrees around a longitudinal axis of the access member.

Neither the Ahmed patent, nor the Makower patent, alone or in combination, disclose or render obvious the claimed subject matter.

Ahmed's surgical instrument 80 has a needle-like body member 84 with an elongated slot 86 in a side wall 84a thereof and a U-shaped channel 88 therein. Ahmed explains that the slot 86 and channel 88 each have a width that is essentially equal to the diameter of the inlet tube 18 so that, with the inlet tube lying in the channel, there is a snug, friction fit. Thus, when the instrument 80 is inserted into the patient's eye, fluid will enter the open end of the inlet tube 18 and flows through the inlet tube 18 rather than between the wall of the channel 88 and the wall of the tube.

The outer wall of Ahmed's surgical instrument 80 does not define a window communicating with its longitudinal bore and a slot communicating with the longitudinal bore and extending from the window to the distal end of the surgical instrument, as recited in claim 20 of the present application. As mentioned above, the Office action appears to concede this point.[2] The Office action alleges, however, that it would have been obvious to modify Ahmed's surgical instrument 80 to include add a window at a proximal end of the slot 86 in Ahmed's surgical instrument 80 in view of what is disclosed in Makower. However, for reasons discussed in detail above with respect to claim 1, Applicant respectfully disagrees.

[2] The Office action states, "Ahmed fails to disclose a window at the proximal end of the slot."

As discussed above, a person of ordinary skill would have had no reason to modify Ahmed's surgical instrument 80 to include an enlarged opening (such as the enlarged opening 36 in Makower's device) because doing so would have been in direct contradiction to the Ahmed's teachings and may have compromised the instrument's effectiveness in performing its intended functions.

Claim 20 should be allowable for at least the foregoing reasons.

Claims 21 and 23 depend from claim 20 and, therefore, should be allowable for at least the same reasons as claim 20.

Claims 3, 19 and 22 were rejected under 35 U.S.C. §103(a) as unpatentable over Ahmed in view of Makower and further in view of U.S. Patent No. 5,312,290 (Gerrone). As discussed below, Applicant disagrees with these rejections.

Claims 3 and 19 depend from claim 1; claim 22 depends from claim 20. Applicant submits that claims 3, 19 and 22 should be allowable for at least the same reasons as the claims from which they depend are allowable.

The Gerrone patent merely discloses a combined pneumo-needle and trocar apparatus that has an obturator stop cock 20. (FIG. 1 and 3:33-36) The Gerrone patent does not disclose anything that would anticipate or render obvious the subject matter of claim 1 or claim 20 discussed above. Nor does the Office action allege anything to the contrary.

Claims 3, 19 and 22 should be allowable for at least the foregoing reasons.

Claim 24 was rejected under 35 U.S.C. §103(a) as unpatentable over Ahmed in view of Makower and Gerrone.

Claims 24 recites subject matter similar to the subject matter discussed above in connection with claim 1 and claim 20. More particularly, claim 24 recites a device that has an elongated access member with an outer wall defining a longitudinal bore. The outer wall has a window communicating with the longitudinal bore a slot communicating with the longitudinal

bore and extending from the window to a distal end. The window defines a radial arc in the range of about 90 degrees to about 180 degrees around a longitudinal axis of the access member. The distal end of the access member is formed so as to minimize perforation of a body lumen.

As discussed above, in reference to claims 1 and 20, the cited references neither disclose nor render obvious the claimed subject matter.

Claim 24 should be allowable for at least the foregoing reasons.

New claims 25 and 26 depend from claim 1 and, therefore, should be allowable for at least the same reasons as claim 1.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The Request for Continued Examination (RCE) fee in the amount of $405 is being paid concurrently herewith on the Electronic Filing System (EFS) by deposit account authorization. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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William P. O'Sullivan
Reg. No. 59,005

Customer Number 26211
Fish & Richardson P.C.
601 Lexington Avenue
52nd Floor
New York, NY 10022
Telephone: (212) 765-5070
Facsimile: (877) 769-7945